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| EXAMINER |
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DAVIS, RUTH A

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PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/689,359
Filing Date: October 20, 2003
Appellant(s): RANGANATHAN, NATARAJAN

Jane Massey Licata
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 3, 2008 appealing from the Office action mailed September 17, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|-------------------------|---------|
| 5,716,615 | Cavaliere Vesely et al. | 02-1998 |
| 5,494,664 | Brassart et al. | 02-1996 |
| 3,950,544 | Fridman | 04-1976 |
| 5,744,134 | Paul | 04-1998 |
| 5,902,578 | Halpin-Dohnalek et al. | 05-1999 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1 – 5, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul (US 5744134) in view of Cavaliere Vesely et al. (US 5716615), Brassart et al. (US 5494664) and/or Fridman (US 3950544).

Appellant claims a nutritional food or product comprising *S. thermophilus*, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the composition has a water activity of less than 0.47 and about 5 – 20 billion CFUs of *S. thermophilus*. The carbohydrate, fat, and protein are each selected from a list. The composition may further comprise at least one probiotic and/or at least one prebiotic, each selected from a list. Appellant further finally claims a method for restoring and maintaining

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gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of *S. thermophilus* and about 2 – 6% prebiotic wherein the composition has a water activity of less than about 0.47 and about 5 – 20 billion CFUs of *S. thermophilus*. Appellant finally claims a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and *S. thermophilus* with pH stability and urea degrading activity, wherein the probiotic provides about 5 – 20 billion CFUs of bacteria.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), beneficial human intestinal microorganism (abstract, col.5 line 60-65), wherein the compositions are powdered (or has low water activity) (col.13-14). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. salivaroos*, *L. brevis*, or *L. plantarum*, or *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilis*, *B. bifidum*, (col.4 line 20-29) or *Streptococci* (col.9 line 44-50). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45).

Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Paul does not specifically teach the beneficial bacteria to include *S. thermophilus*. However, the reference clearly indicates *Streptococci* as beneficial bacteria to the GI tract (col.9,

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line 44-50). Furthermore, at the time of the claimed invention, *S. thermophilus* was a known and used bacteria, effective to benefit the GI tract. In support, Cavaliere Vesely teaches pharmaceutical compositions containing *S. thermophilus*, wherein the composition is effective to treat GI disorders (abstract). In addition, Brassart (abstract, col.3-4) and Fridman (col.3-4) both teach nutritional compositions wherein they contain microbes beneficial to the GI tract such as *S. thermophilus*. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to use *S. thermophilus* in the composition of Paul, as it was a known and used bacteria beneficial to the GI tract, as evidenced by the supporting references.

Paul does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However, Paul teaches that the components of the composition may be varied (column 4, lines 1-52; and column 13, line 47, through column 14, line 38) and readily determined by one of ordinary skill in the art (col.6 line 10-18). Furthermore, the supporting references demonstrate varying amounts of the claimed components. In addition, Paul teaches the compositions may be formulated as powders (col.13-14), suggesting a low water activity as claimed by appellant. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

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Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul in view of Cavaliere Vesely, Brassart and/or Fridman, and further in view of Halpin-Dohnalek (US 5902578).

Appellant claims to a nutritional food or product comprising *S. thermophilus*, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the composition has a water activity of less than 0.47 and about 5 – 20 billion CFUs of *S. Thermophilus*. The carbohydrate, fat, and protein are each selected from a list. The composition may further comprise at least one probiotic and/or at least one prebiotic, each selected from a list; and at least one vitamin and mineral. Appellant claims a food product comprising carbohydrates, 2 – 12% fat, protein, vitamin, mineral, prebiotic and *S. thermophilus* wherein the composition has a water activity of less than about 0.47 and about 5 – 20 billion CFUs of *S. thermophilus*. Appellant further finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of *S. thermophilus* and about 2 – 6% prebiotic wherein the composition has a water activity of less than about 0.47 and about 5 – 20 billion CFUs of *S. thermophilus*. Appellant finally claims a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and *S. thermophilus* with pH stability and urea degrading activity, wherein the probiotic provides about 5 – 20 billion CFUs of bacteria.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), beneficial human intestinal microorganism (abstract, col.5 line 60-65), wherein the compositions are powdered (or has low

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water activity) (col.13-14). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. salivaroos*, *L. brevis*, or *L. plantarum*, or *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilis*, *B. bifidum*, (col.4 line 20-29) or *Streptococci* (col.9 line 44-50). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45). Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Paul does not specifically teach the beneficial bacteria to include *S. thermophilus*. However, the reference clearly indicates *Streptococci* as beneficial bacteria to the GI tract (col.9, line 44-50). Furthermore, at the time of the claimed invention, *S. thermophilus* was a known and used bacteria, effective to benefit the GI tract. In support, Cavaliere Vesely teaches pharmaceutical compositions containing *S. thermophilus*, wherein the composition is effective to treat GI disorders (abstract). In addition, Brassart (abstract, col.3-4) and Fridman (col.3-4) both teach nutritional compositions wherein they contain microbes beneficial to the GI tract such as *S. thermophilus*. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to use *S. thermophilus* in the composition of Paul, as it was a known and used bacteria beneficial to the GI tract, as evidenced by the supporting references.

Halpin-Dohnalek teaches a powdered nutritional composition comprising protein, fat, carbohydrates and the probiotic bacteria *Lactobacillus reuteri*, *L. acidophilis* and

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Bifidobacterium infantis (abstract), minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). Halpin-Dohnalek provides examples of the composition wherein the compositions provide 10×10^9 – 5×10^9 (or 5 – 10 billion) CFUs of *L. reuteri* (example 1).

The references do not teach all of the ingredients together in a single composition in the claimed amounts, with the claimed water activity. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose of maintaining and enhancing GI tract health and function. Further, Paul teaches that the components of the composition may be varied (column 4, lines 1-52; and column 13, line 47, through column 14, line 38) and readily determined by one of ordinary skill in the art (col.6 line 10-18) while the supporting references demonstrate varying amounts of the claimed components (Halpin-Dohnalek, column 4, lines 1-28). In addition, Paul and Halpin-Dohnalek teach the compositions may be formulated as powders (Paul, col.13-14; Halpin-Dohnalek, abstract), suggesting a low water activity as claimed by appellant. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Therefore, the

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invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made, especially in the absence of evidence to the contrary.

(10) Response to Argument

Appellant argues that Paul is drawn to a composition comprising an immunoglobulin to improve GI health wherein the claimed bacteria and components are optional; that Paul does not teach the high amounts of viable CFUs of *S. thermophilus*. Appellant argues that they have appreciated that high amounts of bacteria result in good GI health and may alleviate uremia and that the claimed composition has a long shelf life with viable bacteria due to the amounts of fat. Appellant further argues that the compositions of Paul may include 0% bacteria and can be a liquid, which indicates the variables are not critical or result effective variables that can be optimized. Appellant argues that the secondary references do not cure the deficiencies of Paul as they teach higher or no amounts of *S. thermophilus*; that they do not teach *S. thermophilus* to enhance GI health; and that they do not teach the amounts of fat or water activity.

However, these arguments fail to persuade because the disclosure of Paul clearly indicates the claimed components are included in the composition to maintain and improve GI health. It is noted that while appellant points to column 5, lines 55 – 60 as support that the additional components are optional, it is noted that the cited passage is drawn to additional components included with the immunoglobulin composition itself (PROBIOPLEX), not the bacteria, carbohydrate, fat, protein and prebiotics that are included in the composition for improving GI health, as argued. Paul clearly details the claimed probiotics, prebiotics, carbohydrates, fats and proteins that are included in the compositions for maintaining and

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improving GI health (col.5, 6, abstract, claims). While Paul does not teach the claimed amounts of bacteria, Paul clearly indicates that the beneficial bacteria are included at effective amounts to obtain a desired result (col.6 line 10-20), which is to enhance GI health, and that one in the art could readily determine such amounts (col.6 line 15-20). Moreover, the cited references clearly teach the claimed components for the claimed effects of maintaining and enhancing GI health.

Regarding appellant's arguments that appellant's have appreciated that high amounts of bacteria results in compositions with good GI health and long shelf life, it is noted that the cited references clearly teach the same components together for the same claimed and argued effects. Thus, the claimed compositions do not appear to exhibit a result that is unexpected, but one that is clearly disclosed by the cited references.

Regarding the amount of fat, it is first noted that each of the independent claims do not require a particular amount of fat (i.e. claim 8), or even require fat be present (claims 9 and 10). Thus, the argument is not commensurate in scope with each of the claimed inventions. Regarding the claims that do include an amount of fat, it is noted that appellant fails to provide sufficient evidence that the amount of fat results in an unexpected result, especially in light of the cited references that clearly teach and suggest the various components may be optimized by one in the art.

Regarding appellant's arguments that the compositions of Paul may include 0% bacteria and a liquid, it is maintained that the reference clearly suggests to one of ordinary skill in the art that the effective amounts of beneficial bacteria as well as the water content could be readily determined by one of ordinary skill in the art, as it is expressly stated as such in column 6, and that the examples provide for both liquid and powdered compositions. It is further maintained

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that the beneficial bacteria are clearly indicated as desirable to improve GI health since the abstract, examples and claims all require the presence of beneficial bacteria.

Regarding the secondary references, it is noted that Cavaliere Vesely and Brassart support that amounts of *S. thermophilus* can be optimized as they disclose varying amounts of the bacteria to be beneficial to GI health, and the disclosure of Fridman evidences that *S. thermophilus* was commonly known and used in nutritional compositions as claimed by appellant. Further, Halpin-Dohnalek clearly teaches the claimed amounts of beneficial bacteria that aid in maintaining and restoring GI health. While this reference does not identify *S. thermophilus* as the particular bacteria, the reference clearly supports and evidences that the claimed amounts of beneficial bacteria are effective to maintain and restore GI health as claimed. Moreover, the cited combination of references clearly suggest to one in the art that the claimed bacteria and components were routinely combined and included in nutritional compositions, and were therefore obvious to optimize the amounts thereof with a reasonable expectation for successfully obtaining a nutritional composition as claimed. While the supporting references do not teach the claimed water activity, it is noted that Paul teaches liquid to dry powdered compositions, indicating the combined references teach and suggest to one in the art that the water activity may be optimized in light of the combined teachings.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Ruth A. Davis

/Ruth A. Davis/

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